1632

PATENT

ATTORNEY DOCKET NO. JHU1690-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Wong et al.	Art Unit:	1632
Application No.:	09/708,096	Examiner:	Crouch, D.
Filed:	November 3, 2000		
Title:	BETA SECRETASE TRANSGENIC ORGANISMS AND METHODS OF USE THEREOF		

Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER

Sir:

Transmitted herewith for the above-identified application please find:

1. Response to Restriction Requirement mailed March 15, 2002 (4 pages);

2. Petition for Extension of Time (2 pages);

3. Check no. 517135 in the amount of $980.00;

4. Return Receipt Postcard.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on August 26, 2002, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231

Karen LePari

Karen LePari

Gray Cary:GT 6309286.1
104659-31

A check in the amount of $980.00 is enclosed with this response as the fee for a five-month extension of time. If any additional fees are deemed necessary, the Commissioner is authorized to charge (or apply any credits to) Deposit Account No.: 50-1355. The Examiner is invited to contact Applicant's undersigned representative if there are any questions related to this matter.

Respectfully submitted,

Date: August 26, 2002

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RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Requirement for Restriction mailed March 15, 2002 (Paper No. 5), Applicants respectfully traverse the rejection. 35 U.S.C. allows restriction where two or more independent and distinct inventions are claimed in one application. However, it is Applicants' position that Groups III, XII, XIII, XIV and XIX of the present invention, as divided by the Examiner in Paper No. 5 are so related that they are not patentably independent or distinct.

It is alleged in Paper No. 5 that Group III is patentably distinct from Groups XII, XIII, and XIV in that Group III is to a method for modulating the production of Aβ11-40/42 *in vitro* using an antibody molecule and that the methods of XII-XIV are to methods of diagnosing a risk for having an Aβ11-40/42 accumulating disease. It is alleged that the two are mutually exclusive as the end points of the methods is materially different. It is alleged in Paper No. 5 that Group III is patentably distinct from Group XIX in that the two are related as process of use and product and that because the kit of invention XIX can be used in immuno-purificaton procedures the

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Groups are patentably distinct inventions. Similarly, it is alleged that Groups XII and XIX are patentably distinct, in that the two groups are related as process of use and product and that because the antibody of invention XIX can be used in immuno-purificaton procedures the Groups are patentably distinct inventions. It is also alleged in Paper No. 5 that Groups XIII and XIV are alleged to be mutually exclusive with respect to Group XIX as the methods of inventions XIII and XIV do not require the antibody of XIX and vice versa. Applicants respectfully disagree with these allegations.

By the claimed invention, the importance of BACE1 in the processing of APP and fragments thereof and in Alzheimer's Disease (AD) has become known. Correspondingly, the role of modulation of the BACE1 polypeptide and its substrate APP has also become known. While the uses of this novel discovery are many, it is noted that the claims of Groups III, XII, XIII, XIV and XIX of the present invention all involve use of an antibody specific for BACE1, Aβ11-40/42 or APP. In particular, the Examiner's attention is respectfully drawn to claims 5 of Group III, claim 20 of Group XII, claim 27 of Group XIII, claim 35 of Group XIV, and claim 65 of Group XIX which all claim use of an antibody specific for BACE1, Aβ11-40/42 or APP. As such, the claims of Groups III, XII, XIII, XIV and XIX are so related that they are not independent and distinct inventions.

The use of antibodies in the claims of the invention is well supported throughout the application as filed. The Examiner's attention is respectfully drawn to page 18, lines 16-27 of the specification, which discloses a method of modulation of expression of a BACE1 polypeptide, including by administration of an antibody. Additionally, the Examiner's attention is respectfully drawn to page 26, lines 7-25, which discuss detecting levels of BACE1, Aβ11-40/42 or APP fragments, polypeptides or polynucleotides or diagnosing BACE1 or APP fragments. The specification states that in all of these detection and diagnosis methods, "[w]hen the sample contains protein, the reagent is an antibody protein." Additionally, antibodies are set forth in the specification as useful in the treatment of a disorder (see pages 19 and 22) and in reduction of symptoms of a disorder (see page 22).

Additionally, it is set forth in the Examples section of the specification that numerous experiments were performed using antibodies in practice of the claimed invention. See in particular, Example 6 on pages 55-59 of the specification, where antibodies were used to measure the presence of secreted Aβ1-42 and Aβ1-40 (page 56, lines 5-8). Additionally, it is stated on page 57, lines 5-7 that"...thus antibodies specific to Aβ11-40/42 would prove useful for diagnoses of sporadic AD."

As the claims of Groups III, XII, XIII, XIV and XIX of the present invention are united by the common requirement of antibody administration, it is alleged that those Groups are so related that they are not independent and distinct inventions. Rejoinder of Groups III, XII, XIII, XIV and XIX is respectfully requested.

In the event that the Examiner does not agree that Groups III, XII, XIII, XIV and XIX are not independent and distinct inventions, Applicants elect the claims of Group III, consisting of Claims 1, 2, 4 and 5, drawn to a method for modulating production of Aβ11-40/42 peptide fragments comprising contacting a sample or cell in vitro containing BACE1 and an APP with a BACE1-modulating agent where the modulating agent is a BACE1 antibody, classified in class 435, subclass 29, with traverse. This election is made only in order to comply with the requirement that Applicants make an election in response to the Restriction Requirement mailed March 15, 2002, and not because Applicants believe that the claims, as filed, are patentably distinct.

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Respectfully submitted,

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